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Review

Robotically assisted ablation of atrial fibrillation: A systematic review and meta-analysis

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ABSTRACT

Background: Robotic systems are becoming increasingly common in complex ablation procedures. We conducted systematic review and meta-analysis on the procedural outcomes of Magnetic Navigation System (MNS) in comparison to conventional catheter navigation for atrial fibrillation (AF) ablation.
Methods: An electronic search was performed using multiple databases between 2002 & 2012. Outcomes were: acute and long-term success, complications, total procedure, ablation and fluoroscopic times.
Results: Fifteen studies (11 nonrandomized controlled studies & 4 case series) involving 1647 adult patients were identified. In comparison between MNS and conventional groups, a tendency towards higher acute success was noted with conventional group but with similar long-term freedom from AF (95% vs. 97%, odds ratio (OR) 0.25 (95% confidence interval [CI] 0.06; 1.04, p = 0.057); 73% vs. 75%, OR 0.92 (95% CI 0.69; 1.24, p = 0.59), respectively). A significantly shorter fluoroscopic time was achieved with MNS (57 vs. 86 min, standardized difference in means (SDM) −0.90 (95% CI −1.68; −0.12, p = 0.024)). Longer total procedure and ablation times were noted with MNS (286 vs. 228 min, SDM 0.7 (95% CI 0.28; 1.12, p = 0.001); 67 vs. 47 min, SDM 0.79 (95% CI 0.18; 1.4, p = 0.012), respectively). Overall complication rate was similar (2% vs. 5%, OR 0.48 (95% CI 0.18; 1.26, p = 0.135)), however rate of significant pericardial complication defined either as tamponade or effusion requiring intervention/hospitalization was significantly lower in MNS (0.3% vs. 2.5%, p = 0.005).
Conclusions: Our results suggest that MNS has similar rates of success and possibly superior safety outcomes when compared to conventional manual catheter ablation for AF.

1. Introduction

Atrial fibrillation (AF) is the most common cardiac dysrhythmia, with lifetime risk between 22 and 26% by 80 years of age [1]. Catheter ablation is an established therapeutic alternative in symptomatic AF patients, resistant to anti-arrhythmic medications [2]. Circumferential isolation of the pulmonary veins (PVI) is the mainstay of AF ablation procedure. Many studies have reported acceptable efficacy and safety outcomes of this procedure [3], but length of the procedure, associated large amount of fluoroscopy exposure, along with complication rates have always been a concern. Mechanical complications may occur due to a variety of factors, among them operator and hospital experience with transseptal technique, and with atrial fibrillation in particular. Ablation parameters and technique used may also be important, and perhaps, the stiffness of the ablation catheter may play a role. Novel technologies such as robotically assisted ablation have been developed to enhance the effectiveness and safety of AF ablation. Magnetic Navigation System (MNS) (Stereotaxis Inc., St. Louis, Missouri, USA) is used in both complex and simple ablation procedures with presumed potential improvements in procedural efficacy and safety. Accuracy of the MNS was established in-vitro and in-vivo experiments prior to clinical adoption [4]. Since its first published report in humans in 2003 [5], the data obtained from existing literature regarding the efficacy and safety of this system is inconsistent and limited mostly to small and underpowered trials. As expected for a new and developing technology, there are major differences in ablation generator settings, catheters used, follow-up and ablation protocols reported in existing literature with this system. The effect of these differences can be mitigated by pooling data across a large sample of patients to assess the overall differences on efficacy and safety between novel MNS and conventional technique for AF ablation. We conducted a systematic review and meta-analysis of the available published literature on

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the effectiveness and safety of MNS in comparison to conventional manual navigation for AF ablation.

2. Methods

2.1. Literature search and study identification

An electronic search was performed in accordance with the recommendations of Cochrane collaboration using Cochrane CENTRAL database, Medline, Embase, and Web of Knowledge between 2002 and 2012. The initial search terms were: "catheter ablation" and "magnetic navigation" and "atrial fibrillation". No language restrictions were applied. All references from papers obtained through the databases were reviewed manually. Bibliographies of retrieved articles and published reviews were hand searched for additional publications. The electronic search has been archived and is available on request.

2.2. Study selection and data extraction

We included randomized controlled trials, case series, cohort and case–control studies. The studies were only included in this analysis if they provided data on the outcomes of interest in adult population >18 years old. The selection of studies was assessed independently by three assessors (EC, MS, and AD). We excluded case reports, editorials, letters, replies, reviews and experimental studies.

Some of the studies' qualities were limited in that they were retrospective. We used the Newcastle-Ottawa Scale to further assess the quality of nonrandomized studies [6]. Studies were judged on three broad perspectives: the selection of the study groups, the comparability of the groups, and the ascertainment of either the exposure or outcome of interest for case–control or cohort studies respectively.

Two reviewers (MS, AD) independently extracted the data from published sources; disagreements were resolved by discussion and, when necessary, in consultation with a third person (EC, IL, and DN). The primary outcome measures of the effectiveness were acute and chronic procedural success. Secondary outcomes included procedure and ablation times, total fluoroscopic time, and complication rates. Whenever possible, direct communication with the authors of the papers was undertaken in attempt to obtain the data of interest if presentation in the manuscript was incomplete.

2.3. Definition of outcomes

The duration of procedure was defined as the time from entering to leaving the electrophysiological laboratory;

Acute success was defined as obtaining the acute intra-procedural end points (electrical isolation of all pulmonary veins);

Chronic success was defined as freedom from the arrhythmia (based on symptom and/or electrocardiographic documentation) during the follow-up period.

Although the assessment of acute and chronic success across the trials was not standardized, within each trial the same criteria were applied equally to the treatment groups.

Fluoroscopy time was defined as the total duration of fluoroscopy during the procedure (in minutes) and severe complications were defined as significant pericardial complication (cardiac tamponade or pericardial effusion requiring intervention/hospitalization), stroke/transient ischemic attack (TIA) or significant pulmonary veins stenosis.

2.4. Magnetic Navigation System

Magnetic Navigation System allows manipulation of the ablation catheter using a combination of magnetic steering and mechanical pulling/pushing mechanism. The MNS system has been fully described elsewhere [5]. Two external magnets located on either side of the patient generate a magnetic field (0.08 or 0.1 T). A magnetically enabled catheter incorporates magnets in the distal catheter tip to be manipulated remotely by directional magnetic fields.

The operator can alter the vector of the magnetic field from the control room and the catheter tip will align with this vector allowing the operator to navigate the distal tip of the catheter. In cases where the arrhythmia substrate is located close to critical structures, stored magnetic vectors can be used to re-navigate to spots tagged and stored during the procedure. The magnetic catheter is soft with almost no torsional rigidity and unlikely to perforate with simple forward mechanical pressure [7,8]. The catheter can be either non-irrigated or irrigated.

2.5. Statistics

The random effects model of DerSimonian and Laird was used for combining results from the individual trials. Summary estimates and 95% confidence intervals (CI) for continuous variables were reported as standardized difference in means (SDM), while odds ratios (OR) were reported for dichotomous variables. Statistical significance was set as a p-value less than 0.05. All statistical calculations were performed with the use of Comprehensive Meta-analysis version 2 software (Biostat, Englewood, New Jersey).

3. Results

3.1. Studies characteristics and patient population

Fifteen studies were identified. Available data on clinical outcomes from eleven nonrandomized controlled studies comparing MNS to conventional manual navigation were used in this meta-analysis [7–17]. We identified four case series that reported outcomes of interest [18–21]. The information relevant to the literature search is shown in Fig. 1. In total, 1647 patients were enrolled in these studies. MNS was deployed in 859 patients. Among all studies, average age was similar between MNS and control groups (58 years vs. 51 years, $p = 0.42$). Paroxysmal AF patients accounted for 63% in the MNS, and 66% in the control groups. There were no differences in the left ventricular ejection fraction or left atrial diameter between both groups (58% vs. 60% $p = 0.23$; 44 mm vs. 43 mm $p = 0.32$, respectively). Follow-up period ranged between 90 and 720 days. Different follow-up protocols were used among studies. All protocols used ECG recordings to establish successful ablation with variations based on frequency and duration of recordings performed. A blanking period between 6 weeks and 6 months was applied in some studies. Summaries of the studies and baseline characteristics of the patients in controlled studies and case series are presented in Tables 1 and 2 respectively. Clinically relevant ablation characteristics of the controlled studies and case series are presented in Tables 3 and 4 respectively.

3.2. Outcomes of controlled trials

3.2.1. Primary outcomes

In comparison between MNS and conventional groups, a tendency towards higher acute success was noted with the conventional group but with similar long-term freedom from AF (95% vs. 97%, OR 0.25 (95% confidence interval [CI] 0.06; 1.04, $p = 0.057$); 73% vs. 75%, OR 0.92 (95% CI 0.69; 1.24, $p = 0.59$), respectively) Fig. 2.

3.2.2. Secondary outcomes

A significantly shorter fluoroscopic time was achieved with MNS (57 vs. 86 min, SDM −0.9 (95% CI −1.68; –0.12, $p = 0.024$)) Fig. 3. Longer total procedure and ablation times were noted with MNS (286 vs. 228 min, SDM 0.7 (95% CI 0.28; 1.12, $p = 0.001$); 67 vs. 47 min, SDM 0.79 (95% CI 0.18; 1.4, $p = 0.012$), respectively) Fig. 4. Overall complication rate was similar between both groups (2% vs. 5%, OR 0.48 (95% CI 0.18; 1.26, $p = 0.135$)). Severe complications were encountered in 6 studies [7,9,11,13,15,17]. There was a trend towards lower severe complications in the MNS group (0.4% vs. 3%, OR 0.33 (95% CI 0.097; 1.14, $p = 0.081$)) Fig. 5. There were only 2 cases with significant pericardial complications reported in the MNS group but 20 cases reported in the control group (0.3% vs. 2.5%, $P = 0.005$). One case of TIA was encountered in the MNS group versus two cases were encountered in the control.

3.3. Outcomes of non-controlled trials using magnetic navigation system

Four case series where MNS was deployed in 337 patients were assessed. Average acute and chronic successes were 97% and 68% respectively. An average fluoroscopic time of 25 min was reported. Total procedure time was 178 min with an ablation time of 55 min. Overall complication rate was 3.4%, out of which 2.3% were severe.

3.4. Ablation generator settings

Ablation settings varied among different operators while using MNS. Irrigated ablation catheters were used in all but one study [8]. Average maximum temperature used during ablation with MNS was 47 °C. Along with the temperature applied, the average maximum power used during ablation was 39 W with an average flow rate of 28 mL/min.